Retrospective Study Sample Proposal

Study Protocol Title:

_____

Vascular Low Frequency Disease Consortium (VLFDC) Site Address	David Geffen School of Medicine at UCLA Division of Vascular Surgery 200 Medical Plaza, Suite 526 Los Angeles, CA 90095
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VLFDC topic Co-Investigators (Max 2 per institution)	
Lead Investigator	
Co-Investigator	

A Note from the Investigators

Dear Collaborator,

On behalf of the Vascular Low Frequency Disease Consortium (VLFDC), welcome! We are very excited to be working with you to find ways to _____. Thank you for committing to participate in this project.

This document has been prepared to assist you and your team in preparing your Institutional Review Board (IRB) submission. In the sample proposal, you will find information that IRBs commonly request in their review of retrospective studies that qualify for expedited review. We understand that every IRB has a unique application and varied review process; please use your discretion to modify the sample and accommodate the needs of your IRB.

We are available to provide any additional information that your IRB may request. Please do not hesitate to contact Nakeisha Favors via email at nfavors@mednet.ucla.edu if you need additional assistance or have any questions.

To begin, please fill out and submit the VLFDC signature page. We look forward to working with you.

Sincerely,

Peter F. Lawrence, MD, VLFDC Director
Pflawrence@mednet.ucla.edu

Karen Woo, MD, VLFDC Associate Director
Kwoo@mednet.ucla.edu

Jonathan Bath, MD, VLFDC Associate Director
bathj@health.missouri.edu

VLFDC Signature Page

The signature below provides the necessary assurances that this study will be conducted according to the stipulations of the VLFDC, including all statements regarding confidentiality. This is in compliance with the principles outlined in applicable US Federal regulations and Good Clinical Practice Guidelines (ICH E6 Section 4.5.1, 6.2.5, and 8.2.2).

_____	_____
Name of Institution (please print)	Name of Investigator (please print)
_____	_____
Signature of Investigator	Date Signed

Please sign and send to vlfdc@mednet.ucla.edu

Table of Contents

List of Abbreviations

Project Title

Keywords

Background and Significance

Study Objectives

Study Design
Subject Selection

Inclusion Criteria

Exclusion Criteria

Sample Size

Research Design
This is a retrospective chart review study to abstract data from patients treated for _____ from _____.

Study Procedures
Subject Identification
Subjects will be identified by ICD-9-CM or ICD-10-CM and CPT codes.

CPT	DESCRIPTION

ICD-9/ 10 Code	DESCRIPTION

Procedures Involved
The study does not involve any patient contact and will not impact the care that patients receive. De-identified data regarding the patients will be compiled and analyzed to accomplish the proposed study objectives. Data collection will include _____

Multi-Institutional Research
Up to ____ additional centers may participate in this study. After the data has been collected at a participating institution, the de-identified data will be transmitted securely to a central analytic center located at the David Geffen School of Medicine at UCLA.

Study Duration

We anticipate the review to take up to __ months/years to complete.

Risks and Benefits

Risks to Subjects

As this is a retrospective study, there is no potential for physical risks to subjects. There is a minimal risk of breach of confidentiality that could occur when patient information is collected and analyzed for the proposed study. However, appropriate measures will be taken to minimize the risk as much as possible. All information recorded will be de-identified. This study will abide by all regulations related to protecting human subjects and protected health information.

Potential Benefits to Subjects

There is no direct benefit to the subjects. However, future patients with ____ may benefit from improved care as a result of this study.

Statistics and Data Analysis

Request for Waiver of HIPAA Authorization

This study consists of a retrospective chart review. All patients who fulfill the eligibility criteria will be included. We request a waiver of HIPAA authorization as contacting each patient to request their authorization to access their private health information is not practical and may present a bias in the study as patients who fulfill eligibility criteria may have moved to another area or receive care at a different institution now. All data extracted from patient charts will be de-identified and assigned a unique study number prior to entry into the study database. Protected health information will not be re-used or disclosed to any person or entity. The study results will not be communicated to the subjects included in the study. The results of the proposed study will be used to improve the care of future patients.

Data Security

All research personnel involved in the study will act in accordance with HIPAA regulations. All data will be de-identified at each site before being sent to the centralized database for the multi-institutional study. All data contributed to multi-institutional study will be housed in a secure electronic database located on a password-protected computer at the David Geffen School of Medicine at UCLA. Only the investigators, project coordinator, and data analyst will have access to the de-identified, multi-institutional data. PHI will be maintained at participating sites for the purpose of data verification. Any documents with PHI will be stored in a locked room at each study site for a minimum of 3 years after completion of the study.

Compensation to Subjects

Subjects will not be compensated. There will be no direct contact with patients in this retrospective chart review.

Ethical Considerations

No ethical considerations have been identified as there will be no direct contact with patients before, during, nor after the proposed study.

Conflict of Interest
The investigators have no conflict of interest to report.

Funding Source
There are no plans to apply for grants or additional funding. No funding is required for the completion of this study.

Publication Plan
The plan is to submit the results of this study as an abstract to____, which has a deadline of ____. The remainder of the results will be published in subsequent national Society for Vascular Surgery Annual Meetings, or regional surgical society meetings. All research personnel listed on this protocol will be eligible for authorship in any resulting abstracts and publications in accordance with the qualifications outlined by the International Committee of Medical Journal Editors. The order of authors will be determined prior to manuscript development and depend on each individual's contribution to the study.

References